UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Baltimore Division)

AVENTIS PHARMA DEUTSCHLAND GMBH, et al. Plaintiffs, v. LUPIN LTD., et al. Defendants.	Civil Action No. 1:05-cv-01936-WDQ

FIRST AMENDED COMPLAINT

Plaintiffs, Aventis Pharma Deutschland GmbH ("Aventis") and King Pharmaceuticals, Inc. ("King"), by their attorneys, for their First Amended Complaint against Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively "Lupin"), allege as follows:

Nature of the Action

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and, more particularly, 35 U.S.C. §§ 271(b), 271(e)(2) and 281. This action relates to the Abbreviated New Drug Application No. 77-626 ("Lupin's ANDA") filed by Lupin Ltd. with the United States Food and Drug Administration ("FDA") for approval to market generic versions of King's ALTACE® drug products.

The Parties

2. Aventis is a corporation organized and existing under the laws of Germany, and has a principal place of business at Industriepark Hoechst, Frankfurt am Main, Germany.

3. King is a corporation organized and existing under the laws of Tennessee, and has a principal place of business at 501 Fifth Street, Bristol, Tennessee 37620.

4. On information and belief, Lupin Ltd. is a company organized and existing under the laws of India, having its principal place of business at Laxmi Towers "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai 400 051, India.

5. On information and belief, Lupin Pharmaceuticals, Inc. is a corporation incorporated under the laws of the Commonwealth of Virginia, having its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

6. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Ltd.

7. On information and belief, the acts of Lupin Ltd. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Lupin Pharmaceuticals, Inc.

Jurisdiction and Venue

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

9. This Court has personal jurisdiction over Lupin Ltd. by virtue of the fact that, upon information and belief, Lupin Pharmaceuticals, Inc. is Lupin Ltd.'s designated agent in Maryland, and acted as Lupin Ltd.'s representative U.S. agent in filing Lupin's ANDA with the FDA for approval to market generic versions of King's ALTACE® drug products (See 21 C.F.R. § 314.50(a)(5)) and that Lupin Pharmaceuticals, Inc. participated in the work related to the submission of Lupin's ANDA. Prior to filing this complaint, plaintiffs requested the identity of Lupin Ltd.'s agent responsible for filing Lupin's ANDA discussed above. Lupin, however, has

refused to provide this information. Moreover, upon information and belief, Lupin Ltd. conducts business in this District through its wholly owned subsidiary Lupin Pharmaceuticals, Inc.

10. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. by virtue of the fact that Lupin Pharmaceuticals, Inc.'s principal place of business is in Maryland, and Lupin Pharmaceuticals, Inc. conducts business in Maryland.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patent In Suit

12. United States Patent No. 5,061,722 ("the '722 patent") entitled "Cis,Endo-2-Azabicyclo-[3,3,0]-Octane-3-Carboxylic Acids, A Process for Their Preparation, Agents Containing These Compounds And Their Use" duly and legally issued on October 29, 1991 to inventors Volker Teetz *et al.* by the United States Patent and Trademark Office. A copy of the '722 patent is attached hereto as Exhibit A. The '722 patent claims, *inter alia*, the angiotensin converting enzyme inhibiting compound ramipril.

13. The '722 patent was assigned to Hoechst AG and was subsequently assigned to Aventis. At all times from the issuance of the '722 patent to the present, Aventis or one of its predecessors in interest has been the owner of the '722 patent.

14. King has an exclusive license, *inter alia*, to sell ramipril pharmaceutical products in the United States under the '722 patent. King sells drug products containing ramipril in the United States under the trademark ALTACE®.

Acts Giving Rise To This Action

15. On or about June 8, 2005, plaintiffs received a letter (the "Notification Letter") from Lupin notifying plaintiffs that Lupin had filed a patent certification pursuant to section 505(j)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2). In the Notification Letter, Lupin stated that it had submitted ANDA No. 77-626 to the FDA seeking marketing approval for capsules containing 1.25 mg, 2.5 mg, 5 mg, and 10 mg of ramipril ("Lupin's Ramipril Capsules"[1]).

16. Lupin's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, use and sale of Lupin's Ramipril Capsules prior to the expiration of the '722 patent, which is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" ("Orange Book") as being applicable to King's ALTACE® capsules. On information and belief, Lupin intends to engage and will engage in the commercial manufacture, use and sale of Lupin's Ramipril Capsules promptly upon receiving FDA approval to do so.

17. In its Notification Letter, Lupin stated that its ANDA No. 77-626 contained a "Paragraph IV Certification" that, in Lupin's opinion, the '722 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use or sale of Lupin's Ramipril Capsules.

18. In its Notification Letter, Lupin offered to provide access to certain confidential information and materials within Lupin's ANDA that would allow King and Aventis to confirm Lupin's infringement of the '722 patent. Lupin did not provide this information in its Notification Letter. The parties could not reach agreement on the terms of such confidential

[1] As used herein, the phrase "Lupin's Ramipril Capsules" refers to all capsule strengths set forth in Lupin Notification Letter as well as any other ramipril formulation that is the subject of Lupin's ANDA.

access, and to date Lupin has not provided this information to attorneys for King or Aventis.

Count I : Infringement Count

19. Plaintiffs repeat and reallege the allegations of paragraphs 1-18 as though fully set forth herein.

20. Lupin's submission of its ANDA to obtain approval to engage in the commercial manufacture, use and sale of Lupin's Ramipril Capsules, prior to the expiration of the '722 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2).

21. Unless enjoined by this Court, Lupin, upon FDA approval of Lupin's ANDA, will infringe the '722 patent by making, using, offering to sell, importing, and selling Lupin's Ramipril Capsules in the United States.

22. There is a justiciable controversy between the parties hereto as to infringement of the '722 patent.

23. Lupin had notice of the '722 patent at the time of its infringement. Lupin's infringement has been, and continues to be, willful and deliberate.

24. Lupin's Paragraph IV Certification that, in Lupin's opinion, the '722 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use or sale of Lupin's Ramipril Capsules is baseless.

25. This case is an exceptional one, and King and Aventis are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

26. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

Count II : Inducing Infringement

27. Plaintiffs reallege paragraphs 1 through 26 as if fully set forth herein.

28. Upon information and belief, Lupin Pharmaceuticals, Inc. has infringed the '722 patent under 35 U.S.C. §271(b) by actively inducing Lupin Ltd. to infringe the '722 patent.

Prayer For Relief

WHEREFORE, plaintiffs respectfully request the following relief:

(A) A judgment declaring that Lupin has infringed, and that Lupin's making, using, selling, offering to sell or importing Lupin's Ramipril Capsules and/or its active ramipril ingredient will infringe the '722 patent;

(B) A judgment ordering that the effective date of any FDA approval for Lupin to make, use or sell Lupin's Ramipril Capsules be no earlier than the date on which the '722 patent expires, and expiration of any FDA exclusivities relating to King's ALTACE® drug products;

(C) A judgment permanently enjoining Lupin from making, using, selling, offering to sell, or importing Lupin's Ramipril Capsules and/or its active ramipril ingredient until after the expiration of the '722 patent and any FDA exclusivities relating to King's ALTACE® drug products;

(D) If Lupin engages in the commercial manufacture, use, offer to sell, or sale of Lupin's Ramipril Capsules and/or its active ramipril ingredient prior to the expiration of the '722 patent, a judgment awarding plaintiffs damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(E) Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(F) Costs and expenses in this action; and

(G) Such further and other relief as this Court may deem just and proper.

Respectfu lly submitted,

Date: August 26, 2005

By: /s/

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